

REMARKS

Reconsideration is requested.

Claims 1, 2, 6, 9-13, 15, 16, 20-28, 30-32, 36-41, 48, 50, 51, 55-58 and 62 are pending. Upon entry of the above amendments, claims 1, 15, 16, 22-24, 32, 36-37, 41, 48, 50, 57-58 and 62-65 will be pending. The amendments are presented to place the application in condition for allowance. At a minimum, the claims are submitted to advance prosecution by reducing the issues for appeal, as further detailed below. The amendments are not believed to raise new issues requiring further search and/or consideration. No new matter has been added. Entry of the amendments is requested.

The Examiner's rejoinder and examination of claim 62 is acknowledged, with appreciation.

The Section 112, second paragraph, rejection of claims 10-13, 20-23, 26-28, 30-32 and 36-41 stated on page 6, ¶25 of the Office Action dated August 22, 2005, will be obviated upon entry of the above amendments. The objected-to term has been amended to advance prosecution. Entry of the present Amendment will reduce this issue for appeal. Entry of the Amendment and withdrawal of this rejection are requested.

The Section 112, first paragraph "enablement", rejection of claim 24 stated in ¶26 of the August 22, 2005 Office Action will be obviated by the above amendments which have deleted the phrase "a peptide comprising CDR1, CDR2 and CDR3 of the H chain V region and CDR1, CDR2 and CDR3 of the L chain V region" from claim 24, which is understood to be the basis of the rejection. Entry of the present Amendment will reduce

this issue for appeal. Entry of the Amendment and withdrawal of this rejection are requested.

The following rejections are believed to be obviated by the above amendments, which have added the subject matter of claims 20, 21, 30 and 31 to claim 1:

the Section 103 rejection of claims 1-2, 6, 9-13, 15-16, 24, 26-28, 36-39 and 50-51 over Shitara (USP 5,750,078) [a] in view of Queen (U.S. Patent No. 5,530,101) and Nakamura (Cancer, 80(12 Suppl):2650-2655),

the Section 103 rejection of claims 1-2, 6, 9-13, 15-16, 24, 26-28, 36-39 and 50-51 over Shitara (USP 6,437,098) [b], Queen and Nakamura;

the Section 103 rejection of claims 1, 2, 6, 9-13, 15-16, 24, 26-28, 36-39 and 50-51 over Shitara (EP 0533199 A2) [c], Queen and Nakamura;

the rejection of claims 1, 2, 6, 9-13, 15-16, 24, 26-28, 36-39 and 50-51 under the judicially created doctrine of obviousness-type double patenting over claims 1-4 of U.S. Patent No. 6,437,098 "in view of Queen and Nakamura"; and

the rejection of claims 1, 2, 6, 9-13, 15-16, 24, 26-28, 36-39 and 50-51 under the judicially created doctrine of obviousness-type double patenting over claims 1-2 of U.S. Patent No. 5,750,078 "in view of" Shitara (EP 0533199), Queen (U.S. Patent No. 5,530,101) and Nakamura; and

the rejection of claims 1, 2, 6, 9-13, 15-16, 24, 26-28, 36-39 and 50-51 under the judicially created doctrine of obviousness-type double patenting over claims 1-2 of U.S. Patent No. 6,495,666 "in view of" Shitara, Queen and Nakamura.

Entry of the above amendments and withdrawal of the above art rejections is requested. Entry of the present Amendment will reduce these issues for appeal. Entry of the Amendment and withdrawal of these rejections are requested.

The Section 112, second paragraph, rejection of claims 10-13, 20-23, 26-28, 30-32, 36-41, 50, 55-58 and 62 stated in ¶33 of the Office Action dated August 22, 2005 will be obviated by entry of the above amendments. Entry of the present Amendment will reduce this issue for appeal. Entry of the Amendment and withdrawal of this rejection are requested.

The Section 112, first paragraph, rejections of claim 48 stated in ¶¶34 and 35 of the August 22, 2005 Office Action will be obviated by entry of the present Amendment. Specifically, the amendments, which have been made without prejudice and to advance prosecution, define the H chain V region as one having the amino acid sequence represented by SEQ ID NO:9 and the L chain V region as one having the amino acid sequence in which at least one or more amino acid residue selected from 41st position Gly, 44th position Pro, 83rd position Phe and 87th position Tyr represented by SEQ ID NO:10 is replaced with the amino acids of the original mouse antibody, i.e., Asp, Val, Ile and Phe, respectively.

The applicants submit that in the item 3(1) of Example 1 of the present application, the H chain V region having the amino acid sequence represented by SEQ ID NO:9 and the L chain V region having the amino acid sequence represented by SEQ ID NO:10 were prepared. In the items 5(1) and 5(2) of Example 1, the vectors in which one or more of the amino acid residues at positions 7, 8, 12, 41, 44, 72, 77, 83 and 87 in the amino acid sequences represented by SEQ ID NO:10 were changed were

prepared. As described in the item 5(3) of Example 1, increased binding activity in comparison with the anti-GD3 CDR-grafted antibodies before modification was obtained by the changes at positions 41, 44, 83 and 87 of the amino acid residues (i.e., pT641HLCDRM-6, pT641HLCDRM-9 and pT641HLCDRM-69) (cf. Fig. 11). Accordingly, the applicants submit that the subject matter of claim 48 is adequately described in and enabled by the present specification, and that the ordinarily skilled person would understand that the antibody having high activity was obtained by the changes of the amino acids recited in claim 48 and would be capable of preparing the humanized antibody recited in claim 48 based on the description in the present specification without undue experimentation.

Entry of the present Amendment and withdrawal of the Section 112, first paragraph, rejections of claim 48 are requested. Entry of the present Amendment will reduce these issues for appeal. Entry of the Amendment and withdrawal of these rejections are requested.

Claim 63 corresponding to the humanized antibody or the antibody fragment thereof contained in the antibody conjugate in claim 1 has been added above. Support for the claim may be found throughout the specification. No new matter has been added. New claims have not been added without canceling a corresponding number of rejected claims. Entry and allowance of the new claims are also requested.

The paragraph bridging pages 60 and 61 has been amended. Specifically, the applicants submit that the amino acid sequence represented by SEQ ID NO:10 corresponds to the amino acid sequence of hKM641L in which the 49th position Tyr, the 65th position Ser and the 71st position Phe in the FR amino acid sequence of LV.0

were replaced by amino acid residues of positions corresponding to the VL of anti-GD3 mouse antibody KM641. According to the amino acid sequence represented by SEQ ID NO:10, the amino acids at the 49th, 65th and 71st positions are Phe, Gly and Tyr, respectively, whereas according to the description at page 61, line 21 in the present specification, they are Tyr, Ser and Phe, respectively. This contradiction was caused by the inadvertent, incorrect description at page 61, line 21 in the present specification. That is, the amino acid sequence represented by SEQ ID NO:10 is correct. Therefore, in order to resolve the contradiction, the amino acids "Tyr, Ser and Phe" at page 61, line 21 in the present specification should be replaced with -- Phe, Gly and Tyr-- which are recited in SEQ ID NO:10.

Entry of the present Amendment is requested. The amended claims are submitted to be in condition for allowance and a Notice to that effect is requested.

The Examiner is requested to contact the undersigned in the event anything further is required in this regard.

Respectfully submitted,

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